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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,437	01/20/2004	Hans J. Hoorn	SYN-0018B	1154

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EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/759,437

Applicant(s)

HOORN ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application is a divisional of SN 10/274,051.

Claims 1-25 are pending.

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is inoperative and therefore lacks utility. Please note that to the extend the “treating” is mere mixing of formula I with a deformylation agent, the process provided no utility.

It is recommended that the process steps and products be incorporated.

3. Claims 1-7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “treating” is indefinite. It is unclear what does “treating” includes. To the extend it includes no activity, the above 101 rejection would apply. To the extend it includes *neet* reaction, the following 112 first paragraph will apply.

4. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as well as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention or to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims encompassed the process operating in *neet* conditions for which no description or enabling support can be found in the specification.

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21 rejected under 35 U.S.C. 102(b) as being anticipated by Ward et al. US 5,872,132 (recited on 1449).

Ward et al. disclosed paroxetine hydrochloride anhydrate used in treating alcoholism, anxiety etc. see col. 6, lines 33-59. The specification has explicitly disclosed that compound of formula I is an “impurity” of paroxetine hydrochloride. Therefore, when person in need thereof ingest the drug as described by Ward et al. ‘132, they are using the claimed process because the step of deformylation with acid in an aqueous solution is innately being practice. Further, to the extend that the impurity/drug ratio innately 99.97% or more drug and 0.03% or less formula I, the percentages are innately anticipated also.

Ward. et al. disclosed pharmaceutical composition comprising paroxetine hydrochloride anhydrate with dosages anticipating the instant dosage (see col. 7, lines 15-32). Because formula I is “impurity” of paroxetine hydrochloride, the composition of Ward et al. ‘132 would be innately containing formula I with or without knowing what chemical structure of the impurity is. Further, to the extend that the impurity/drug ratio innately 99.97% or more drug and 0.03% or less formula I, the percentages are innately anticipated also.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. US 5,872,132 or Ward et al. in view of Rowe or Sergeant pulp & Chemical Co.

Determination of the scope and content of the prior art (MPEP §2141.01)

Ward et al. '132 disclosed process and products of the claims because an impurity is innately in the product with or without knowing what chemical nature or structural formula the impurity is. Even if the process of making the drug of '132 resulted in discrepancy of impurity content,

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art and the instant claims is that the chemical nature/structural formula of the impurity is explicitly named. Even if the process of making the drug of '132 resulted in discrepancy of impurity content, such difference is mere by quantity not by kind.

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art in possession of the Ward '132 is in possession of the instant claims because the Ward '132 innately disclosed the claimed process as delineated supra, even if the process of making the drug of '132 resulted in discrepancy of impurity content, such difference is mere by quantity not by kind. Further, the Ward et al. '132 disclosed the instantly claimed composition with conventional excipients without naming the specific ones of the dependent claims. The handbook or catalog of pharmaceutical excipients clearly provided evidence that the specific name ingredients are conventional excipients and would be expected to be included in the Ward '132 reference implicitly. The picking of more limited excipients among the many alternative choices is considered prima facie obvious. In re Lemin 141 USPQ 814.

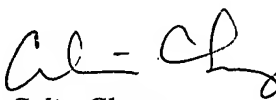
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Sept. 26, 2006


Celia Chang
Primary Examiner
Art Unit 1625